UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

CÉSAR CASTILLO, INC., individually and on behalf of all those similarly situated,

Plaintiff,

v.

FOUGERA PHARMACEUTICALS, INC.; SANDOZ, INC.; NOVARTIS INTERNATIONAL AG; AKORN, INC.; HI-TECH PHARMACAL CO., INC.; PERRIGO COMPANY PLC; TARO PHARMACEUTICAL INDUSTRIES, LTD.; TARO PHARMACEUTICALS USA, INC.; WOCKHARDT LTD.; and MORTON GROVE PHARMACEUTICALS, INC.,

Defendants.

Civil Action No. 1:16-cv-10063

CLASS ACTION COMPLAINT

JURY TRIAL DEMANDED

Plaintiff César Castillo, Inc. ("Plaintiff") files this civil action pursuant to Section 1 of the Sherman Act, Section 4 of the Clayton Act, and Rule 23 of the Federal Rules of Civil Procedure, for damages, costs of suit, and other relief as may be just and proper, on behalf of itself and a class of those similarly situated ("Class" as defined below) against defendants Fourgera Pharmaceuticals, Inc.; Sandoz, Inc.; Novartis International AG; Akorn, Inc.; Hi-Tech Pharmacal Co., Inc.; Perrigo Company plc; Taro Pharmaceutical Industries, Ltd.; Taro Pharmaceuticals USA, Inc.; Wockhardt Ltd.; and Morton Grove Pharmaceuticals, Inc. ("Defendants") for Defendants' conspiracy to artificially fix, raise, maintain and/or stabilize the prices of generic clobetasol propionate topical ointment 0.05%; topical solution 0.05%; topical gel 0.05%; topical cream 0.05% and emollient 0.05% (together "Clobetasol"). Based upon personal knowledge, information, belief, and investigation of counsel, Plaintiff specifically alleges as follows.

INTRODUCTION

1. Beginning no later than July 1, 2014, the major U.S. manufacturers of Clobetasol conspired to artificially fix, raise, maintain and/or stabilize the prices of Clobetasol sold throughout the United States, in violation of Section 1 of the Sherman Act.

2. Plaintiff seeks to represent a Class consisting of all persons in the United States who purchased Clobetasol directly from Defendants during the period beginning July 1, 2014, and through the present.

3. Clobetasol is a high-potency prescription corticosteroid used in the treatment of various skin disorders including eczema, psoriasis, dermatitis and vitiligo. It is reportedly one of the most prescribed dermatological drugs in the United States.

4. Clobetasol is not a new compound. It has been available on the market since 1994. For most of that time, it has been competitively priced significantly below its branded counterpart. As discussed below, this is because the presence of generic drugs usually results in vigorous price competition, benefiting consumers through lower prices.

5. Beginning in July 2014, Defendants substantially increased the price of Clobetasol, in unison. Those increases were the result of an agreement among Defendants to increase pricing and restrain competition for the sale of Clobetasol in the United States.

6. The agreement was furthered by discussions at Generic Pharmaceutical Association ("GPhA") meetings in Orlando, Florida, and North Bethesda, Maryland in February and June 2014, respectively. The meetings were attended by executives from each of the Defendants. Throughout the Class Period, Defendants' executives regularly attended meetings and events sponsored by the GPhA. Prior to July 2014, the average price in the U.S. paid for Clobetasol was remarkably stable. In July 2014, following the June GPhA Meeting, Defendants collectively raised Clobetasol prices by extraordinary amounts.

7. As noted by The U.S. Government Accountability Office ("GAO") [1] and price data developed by the National Association of State Medicaid Directors, National Drug Acquisition Cost data ("NADAC")[2], Clobetasol has experienced "extraordinary price increases:"

a. ***Clobetasol 0.05% cream.*** The average price for 15g Clobetasol 0.05% cream increased by 1194%; the average price for 30g Clobetasol 0.05% cream increased by

---

[1] *See* United States Government Accountability Office, Report of Congressional Requesters, Generic Drugs Under Medicare, Part D Generic Drug Prices Declined Overall, but Some Had Extraordinary Price Increases (August 2016) at 37, available at http://www.gao.gov/assets/680/679055.pdf.

[2] *See* NADAC (National Average Drug Acquisition Cost) weekly reference data from November 2013 to current week available at https://data.medicaid.gov/Drug-Prices/NADAC-National-Average-Drug-Acquisition-Cost-/a4y5-998d.

1154%; the average price for 45g Clobetasol 0.05% cream increased by 1489%; and the average price for 60g Clobetasol 0.05% cream increased by 1492%.

b. ***Clobetasol 0.05% gel.*** The average price for 15g Clobetasol 0.05% gel increased by 979%; the average price for 30g Clobetasol 0.05% gel increased by 1286%; and the average price for 60g Clobetasol 0.05% gel increased by 1967%.

c. ***Clobetasol 0.05% ointment.*** The average price for 15g Clobetasol 0.05% ointment increased by 1851%; the average price for 30g Clobetasol 0.05% ointment increased by 1838%; the average price for 45g Clobetasol 0.05% ointment increased by 1112%; and the average price for 60g Clobetasol 0.05% ointment increased by 1712%.

d. ***Clobetasol 0.05% solution***. The average price for 25ml Clobetasol 0.05% solution increased by 482%; and the average price for 50ml Clobetasol 0.05% solution increased by 1204%.

e. ***Clobetasol 0.05% emollient.*** The average price for 15g Clobetasol 0.05% emollient increased by 594%; the average price for 30g Clobetasol 0.05% emollient increased by 609%; and the average price for 60g Clobetasol 0.05% emollient increased by 914%.

8. Defendants' price increases were substantially in lockstep. Clobetasol prices remained at supra-competitive levels throughout the Class Period.

9. Defendants' price increases were contrary to their respective unilateral self-interests. Like any generic drug, Clobetasol is a commodity product. Therefore, absent a conspiracy or factors justifying a price increase, if any manufacturer substantially increased the price of Clobetasol, its competitors would not be expected to increase their prices by similar amounts, but would be expected seek to sell more Clobetasol to that manufacturer's customers. In other words, it would be contrary to any manufacturer's unilateral self-interest to substantially

increase its price for Clobetasol unless it had agreed with the other manufacturers that they would do the same.

10. The only factors that would have justified such price increases would have been a significant increase in the costs of making Clobetasol, a significant decrease in the supply of Clobetasol, or a significant increase in demand for Clobetasol. None of those transpired in 2014. Absent these factors, substantial price increases would have been contrary to each Defendant's unilateral self-interest absent the existence of a cartel.

11. Defendants' dramatic and unexplained price increases have resulted in extensive scrutiny by the United States Congress and federal and state regulators.

12. No later than November 3, 2014, the Antitrust Division of the United States Department of Justice ("DOJ") commenced a wide-ranging investigation into generic drug manufacturers' marketing and pricing practices, and has caused grand jury subpoenas to be issued to various Defendants in connection with their investigation. DOJ subpoenas were issued to many generic drug manufacturers, including Defendants Sandoz and Taro.

13. On December 14, 2016, the DOJ unsealed criminal informations against two former senior executives of generic drug manufacturer Heritage Pharmaceuticals Inc. for violations of Section 1 of the Sherman Act for their roles in conspiracies to fix prices, rig bids, and allocate customers for generic drugs Glyburide and Doxycycline Hyclate DR. *See United States v. Glazer*, No. 16-cr-506 (E.D. Pa.) and *United States v. Malek*, No. 16-cr-508 (E.D. Pa.). The DOJ is reportedly preparing additional cases involving other generic drugs.

14. On December 15, 2016, the attorneys general of several states filed a civil action alleging federal antitrust violations against Mylan and other sellers of the generic drugs

Glyburide and Doxycycline Hyclate DR. *See State of Connecticut v. Aurobindo Pharma USA, Inc.*, No. 16-cv-2056 (D. Conn.) (the "State AG Action").

15. According to the complaint in the State AG Action, the information developed through the AGs' investigation (which is ongoing) uncovered evidence of a broad, well-coordinated and long-running series of schemes to fix the prices and allocate markets for generic pharmaceuticals, beyond Glyburide and Doxycycline Hyclate DR. The complaint alleges that the conspiracies implicate numerous manufacturers.

16. In addition, the Connecticut Attorney General has issued subpoenas and interrogatories to generic drug manufacturers.

JURISDICTION AND VENUE

17. This action arises under section 1 of the Sherman Act, 15 U.S.C. § 1 and section 4 of the Clayton Act, 15 U.S.C. § 15(a), and seeks to recover treble damages, costs of suit and reasonable attorneys' fees for the injuries sustained by Plaintiff and members of the Class resulting from Defendants' conspiracy to restrain trade in the United States. The Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1337(a), 1407, and 15 U.S.C. § 15.

18. Venue is proper in this District pursuant to 15 U.S.C. §§ 15(a), 22 and 28 U.S.C. §§ 1391(b), (c), and (d) because, during the Class Period, Defendants resided, transacted business, were found, or had agents in this District, and a substantial portion of their activity that affected the interstate trade and commerce discussed below has been carried out in this District.

19. During the Class Period, Defendants sold and shipped Clobetasol in a continuous and uninterrupted flow of interstate commerce, including in this District. Defendants' conduct had direct, substantial, and reasonably foreseeable effects on interstate commerce in the United States, including in this District.

20. This Court has *in personam* jurisdiction over Defendants because each, either directly or through the ownership and/or control of its subsidiaries, *inter alia*: (a) transacted business throughout the United States, including in this District; (b) participated in the sale and distribution of Clobetasol throughout the United States, including in this District; (c) had and maintained substantial aggregate contacts with the United States as a whole, including in this District; or (d) was engaged in an illegal price-fixing conspiracy that was directed at, and had a direct, substantial, reasonably foreseeable and intended effect of causing injury to, the business or property of persons and entities residing in, located in, or doing business throughout the United States, including in this District. Defendants also conduct business throughout the United States, including in this District, and they have purposefully availed themselves of the laws of the United States.

21. By reason of the unlawful activities alleged herein, Defendants substantially affected commerce throughout the United States, causing injury to Plaintiff and members of the Class. Defendants, directly and through their agents, engaged in activities affecting all states, to restrict output and fix, raise, maintain and/or stabilize prices in the United States for Clobetasol, which unreasonably restrained trade and adversely affected the market for Clobetasol.

22. Defendants' conspiracy and unlawful conduct described herein adversely affected persons and entities in the United States who directly purchased Clobetasol manufactured by Defendants, including Plaintiff and the members of the Class.

PARTIES

A. Plaintiff

23. Plaintiff César Castillo, Inc. is a corporation organized under the laws of the Commonwealth of Puerto Rico, with its principal place of business and headquarters located at

Bo. Quebradas Arena, Rd. #1 Km. 26.0, Rio Piedras, Puerto Rico, 00926. During the Class Period, Plaintiff purchased Clobetasol directly from one or more Defendants. As a direct and proximate result of Defendants' collusion, manipulative conduct, and unlawful acts, Plaintiff was injured in its business or property.

B. Defendants

24. Defendant Fougera Pharmaceuticals Inc. ("Fougera") is a New York corporation with its principal place of business located at 60 Baylis Road, Melville, New York 11747. Fougera is a specialty dermatology generic pharmaceutical company that markets and sells generic Clobetasol throughout the United States. Fougera is a wholly owned subsidiary of Defendant Sandoz, Inc. During the Class Period, Fougera sold Clobetasol products to customers in this District and throughout the United States.

25. Defendant Sandoz, Inc. ("Sandoz"), is a Colorado corporation with its principal place of business located at 100 College Road West, Princeton, New Jersey 08540. Sandoz is a global leader in generic pharmaceuticals and biosimilars, and is a subsidiary of Defendant Novartis AG. Sandoz acquired Fougera in July 2012 for $1.5 billion in cash, making Sandoz the top generic dermatology medicines company globally and in the United States. During the Class Period, Sandoz, through Fougera, sold Clobetasol products to customers in this District and throughout the United States.

26. Defendant Novartis International AG ("Novartis"), is a Swiss multinational pharmaceutical company with its principal place of business located at Forum 1, Novartis Campus, CH-4056 Basel, Switzerland. Novartis, through its subsidiaries Fougera and Sandoz, manufactures its dermatology products at locations in Hicksville and Melville, New York. During the Class Period, through its subsidiaries Fougera and Sandoz, Novartis sold Clobetasol

products to customers in this District and throughout the United States. Novartis maintains an office in this District at 230 Park Avenue, New York, NY 10169.

27. Fougera, Sandoz, and Novartis will be referred to collectively herein as "Fougera."

28. Defendant Hi-Tech Pharmacal Co., Inc. ("Hi-Tech Pharmacal") is a Delaware corporation with its principal place of business located at 369 Bayview Avenue, Amityville, New York 11701 and wholly owned subsidiary of Defendant Akorn, Inc. Hi-Tech Pharmacal acquired five Abbreviated New Drug Applications ("ANDA") for clobetasol propionate .05% (ointment, solution, cream, emulsion cream, and gel) from DFB Pharmaceuticals, Inc. in or around 2009. In April 2014, Akorn, Inc. completed its acquisition of Hi-Tech Pharmacal for approximately $650 million. During the Class Period, Hi-Tech Pharmacal sold Clobetasol products to customers in this District and throughout the United States.

29. Defendant Akorn, Inc. ("Akorn") is a Louisiana corporation with its principal place of business located at 1925 W. Field Court, Suite 300, Lake Forest, Illinois 60045. Akorn completed its acquisition of Hi-Tech Pharmacal in April 2014, in part to broaden its product line into topical creams and ointments. During the Class Period, as a result of its acquisition of Hi-Tech Pharmacal, Akorn sold Clobetasol products to customers in this District and throughout the United States.

30. Hi-Tech Pharmacal and Akorn will be referred to herein as "Hi-Tech."

31. Defendant Perrigo Company plc ("Perrigo") is incorporated under the laws of Ireland with its principal place of business located at Treasury Building, Lower Grand Canal St., Dublin 2, Ireland. Perrigo's North American base of operations is located at 515 Eastern Avenue, Allegan, Michigan 49010, where Perrigo's domestic subsidiaries (Perrigo Company, a holding

company; Perrigo Pharmaceuticals Co. and L. Perrigo Co., pharmaceuticals manufacturers; and Perrigo Sales Corp., a sales company), all Michigan corporations, are also located. Perrigo's prescription drug business focuses primarily on the manufacture and sale of extended topical prescription pharmaceuticals, such as Clobetasol. Perrigo New York, Inc., a Delaware corporation, manufactures Perrigo's cream and ointment tubes, producing more than 50 million tubes annually. The officers and directors of Perrigo and these domestic Perrigo subsidiaries have been identical or substantially overlapping throughout the Class Period. During the Class Period, Perrigo, through its domestic subsidiaries, sold Clobetasol products to customers in this District and throughout the United States.

32. Defendant Taro Pharmaceuticals USA, Inc. ("Taro USA") is a New York corporation with its principal place of business located at 3 Skyline Dr., Suite 120, Hawthorne, New York 10532. Taro USA is a wholly-owned subsidiary of Defendant Taro Pharmaceutical Industries Ltd. During the Class Period, Taro USA sold Clobetasol products to customers in this District and throughout the United States.

33. Defendant Taro Pharmaceutical Industries Ltd. ("Taro Israel") is an Israeli company with its principal place of business located at 14 Hakitor Street, PO Box 10347, Haifa Bay, 2624761, Israel. Voting power in Taro Israel is 79.3% controlled by Sun Pharmaceutical Company, Ltd. ("Sun"). Defendant Taro USA is a wholly-owned subsidiary of Defendant Taro Israel. During the Class Period, Taro Israel, through its subsidiary Taro USA, sold Clobetasol products to customers in this District and throughout the United States.

34. Taro USA and Taro Israel will be referred to herein as "Taro."

35. Defendant Wockhardt Ltd. ("Wockhardt") is an international pharmaceutical and biotechnology company headquartered with its principal place of business located at Wockhardt

Towers, Bankra Kurla Complex, Bandra (East), Mumbai, Maharashtra 400051, India. Wockhardt maintains manufacturing plants and substantial operations in the United States, including its wholly-owned subsidiary Morton Grove Pharmaceuticals, Inc. During the Class Period, Wockhardt sold Clobetasol products through Morton Grove Pharmaceuticals, Inc. to customers in this District and throughout the United States.

36. Defendant Morton Grove Pharmaceuticals Inc. ("Morton Grove Pharma") is a Delaware corporation with its principal place of business located at 6451 Main Street, Morton Grove, Illinois 60053. Morton Grove Pharma is a wholly-owned subsidiary of Wockhardt. During the Class Period, Morton Grove Pharma sold Clobetasol to customers in this District and throughout the United States.

37. Wockhardt and Morton Grove Pharma are collectively referred to herein as "Morton Grove."

38. Various other entities and individuals currently unknown to Plaintiff may have also participated as co-conspirators in the acts complained of and/or performed acts that aided and abetted and/or otherwise furthered the conspiracy's objectives and unlawful conduct alleged herein.

39. The wrongful acts alleged to have been done by any one Defendant or co-conspirator were authorized, ordered, or done by its directors, officers, managers, agents, employees, or representatives while actively engaged in the management, direction, or control of such Defendant's or co-conspirator's affairs.

CLASS ALLEGATIONS

40. Plaintiff brings this action on behalf of itself and, pursuant to Federal Rules of Civil Procedure 23(a) and 23(b)(3), as representative of a class (the "Class") defined as follows:

> All persons who or entities which purchased Clobetasol directly from any of the Defendants, or any current or former subsidiary or affiliate thereof, or any co-conspirator, in the United States, during the period from and including July 1, 2014 through the present. Excluded from the Class are Defendants and their officers, directors, management, employees, subsidiaries, or affiliates, and all governmental entities.

41. The Class Members are so numerous and geographically dispersed that joinder of all members is impracticable.

42. Plaintiff's claims are typical of the claims of the other Class Members. Plaintiff and other Class members have all sustained damage in that, during the Class Period, they purchased Clobetasol at artificially maintained, non- competitive prices, established by the Defendants' actions in connection with the violations alleged herein.

43. Plaintiff will fairly and adequately protect the interests of all Class Members. Plaintiff has purchased Clobetasol directly from at least one of the Defendants. Plaintiff has retained counsel competent and experienced in class action and antitrust litigation. Plaintiff's interests are coincident with, and not antagonistic to, the interests of the other Class Members.

44. Common questions of law and fact exist with respect to all Class Members and predominate over any questions solely affecting individual members. The common legal and factual questions, which do not vary among Class Members include, but are not limited to, the following:

(a) Whether and to what extent Defendants and their co-conspirators engaged in a contract, combination, or conspiracy to fix, raise, maintain, or stabilize the prices of Clobetasol in the United States;

(b) The scope and duration of the contract, combination, or conspiracy, the identity of its participants, and the acts undertaken in its furtherance;

(c) The effect of the contract, combination, or conspiracy on the prices of

Clobetasol in the United States during the Class Period;

(d) Whether and to what extent Defendants' conduct resulted in supracompetitive prices for Clobetasol;

(e) Whether and to what extent Defendants' conduct injured Plaintiff and other Class Members; and

(f) The appropriate measure of damages sustained by Plaintiff and other Class Members.

45. A class action is superior to any other method for the fair and efficient adjudication of these issues, as joinder of all members is impracticable. The damages suffered by many Class Members are small in relation to the expense and burden of individual litigation, and therefore, it is highly impractical for such Class Members to individually attempt to redress the wrongful anticompetitive conduct alleged herein.

INTERSTATE TRADE AND COMMERCE

46. Defendants are the leading manufacturers and suppliers of Clobetasol sold in the United States.

47. Clobetasol products are produced by or on behalf of Defendants or their affiliates in the United States and/or overseas.

48. During the Class Period, Defendants, directly or through one or more of their affiliates, sold Clobetasol throughout the United States in a continuous and uninterrupted flow of interstate commerce, including through and into this District.

49. The activities of Defendants and their co-conspirators were within the flow of, intended to, and had a substantial effect on interstate commerce in the United States.

50. Defendants and their co-conspirators' conduct, including the marketing and sale of Clobetasol, took place within, has had, and was intended to have, a direct, substantial, and reasonably foreseeable anticompetitive effect upon interstate commerce within the United States.

51. The conspiracy alleged in this Complaint has directly and substantially affected interstate commerce in that Defendants deprived Plaintiff of the benefits of free and open competition in the purchase of Clobetasol within the United States.

52. Defendants' agreement to inflate, fix, raise, maintain, or artificially stabilize prices of Clobetasol, and their actual inflating, fixing, raising, maintaining, or artificially stabilizing Clobetasol prices, were intended to have, and had, a direct, substantial, and reasonably foreseeable effect on interstate commerce within the United States and on import trade and commerce with foreign nations.

FACTUAL ALLEGATIONS

A. Overview of Generic Drug Market

1. Generic drugs lead to lower prices

53. Generic drugs typically provide consumers with a lower cost alternative to brand-name drugs while providing the same treatment. Specifically:

> A generic drug is the same as a brand name drug in dosage, safety, strength, how it is taken, quality, performance, and intended use. Before approving a generic drug product, FDA requires many rigorous tests and procedures to assure that the generic drug can be substituted for the brand name drug. The FDA bases evaluations of substitutability, or "therapeutic equivalence," of generic drugs on scientific evaluations. By law, a generic drug product must contain the identical amounts of the same active ingredient(s) as the brand name product. Drug products evaluated as "therapeutically equivalent" can be expected to have equal effect and no difference when substituted for the brand name product.[3]

[3] FDA, Generic Drugs: Questions and Answers, *available at* http://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm100100.htm.

54. Further, "[d]rug products classified as therapeutically equivalent can be substituted with the full expectation that the substituted product will produce the same clinical effect and safety profile as the prescribed product."[4]

55. Generic versions of brand drugs are priced significantly below the brand versions. Because of the price differentials, and other institutional features of the pharmaceutical market, generic versions are liberally and substantially substituted for their brand counterparts. In every state, pharmacists are permitted (and, in some states, required) to substitute a generic product for a brand product unless the doctor has indicated that the prescription for the brand product must be dispensed as written. States adopted substitution laws following the federal government's 1984 enactment of the Hatch-Waxman Act (discussed in more detail below).

56. The FDA has recognized that "[g]eneric competition is associated with lower drug prices[.]"[5] A Federal Trade Commission study reached the same conclusion finding that in a "mature generic market, generic prices are, on average, 85% lower than the pre-entry branded drug prices."[6] Economic literature in the healthcare market further confirms that competition by generic products results in lower prices for consumers. In the period before generic entry, a brand drug commands 100% of the market share for that drug and the brand manufacturer can set the price without the impact of competitive market forces. Once the first generic enters the

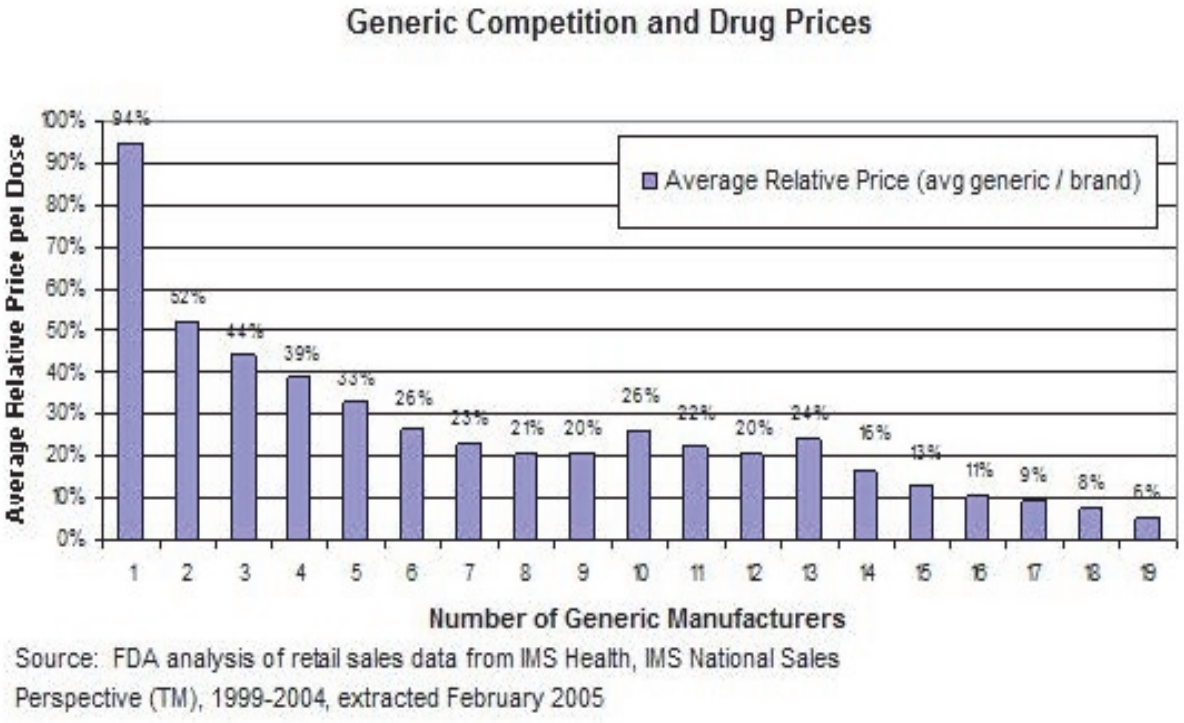
---

[4] *Id.*

[5] FDA, Generic Competition and Drug Prices, *available at* http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm.

[6] FTC, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS, at 8 (Jan. 2010), *available at* https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf.

market, however, a brand drug rapidly loses sales, on average 90% within a year.[7] As more generic manufacturers enter the market, prices for generic versions of a drug predictably will continue to decrease because of competition among the generic manufacturers, and the loss of sales volume by the brand drug to the corresponding generic accelerates as more generic options are available to purchasers:[8]



57. A mature generic market, such as the markets for doxycycline and digoxin, has several generic competitors. Due to the fact that each generic is readily substitutable for another generic of the same brand drug, the products behave like commodities, with pricing being the

[7] *Id.*

[8] *See, e.g.,* Ernst R. Berndt et al., *Authorized Generic Drugs, Price Competition, and Consumers' Welfare,* HEALTH AFFAIRS, 26, no. 3 (2007):790-799.

main differentiating feature and the basis for competition among manufacturers.[9] Over time, generics' pricing nears the generic manufacturers' marginal costs.

58. Generic competition usually enables purchasers to (a) purchase generic versions of the brand drug at a substantially lower price than the brand drug, and/or (b) purchase the brand drug at a reduced price. Generic competition to a single blockbuster brand drug product can result in billions of dollars in savings to direct purchasers, consumers, insurers, local, state, and federal governments, and others. Indeed, one study found that the use of generic medicines saved the United States healthcare system $254 billion in 2014 alone, and $1.68 trillion between 2005 and 2014.[10]

2. How generic drugs come to market

59. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), manufacturers that create a new drug must obtain FDA approval to sell the product by filing a New Drug Application ("NDA"). 21 U.S.C. §§ 301-392. An NDA must include specific data concerning the safety and effectiveness of the drug, as well as information on applicable patents. 21 U.S.C. § 355(a), (b).

60. The Hatch-Waxman Act, enacted in 1984, simplified the regulatory hurdles for

---

[9] *See, e.g.*, FTC, AUTHORIZED GENERIC DRUGS: SHORT-TERM EFFECTS AND LONG-TERM IMPACT, at 17 (Aug. 2011) ("[G]eneric drugs are commodity products marketed to wholesalers and drugstores primarily on the basis of price."), *available at* https://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf; Congressional Budget Office, "How Increased Competition From Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry" (July 1998), *available at* https://www.cbo.gov/sites/default/files/105th-congress-1997-1998/reports/pharm.pdf.

[10] Generic Pharmaceutical Association, *Generic Drug Savings in the U.S.*, at 1 (2015), *available at* http://www.gphaonline.org/media/wysiwyg/PDF/GPhA_Savings_Report_2015.pdf.

prospective generic manufacturers by eliminating the need for them to file lengthy and costly NDAs.[11] Hatch-Waxman allows a manufacturer seeking approval to sell a generic version of a brand drug to file an Abbreviated New Drug Application ("ANDA"). An ANDA relies on the scientific findings of safety and effectiveness included in the brand manufacturer's NDA, and must show that the generic drug contains the same active ingredient(s), dosage form, route of administration, and strength as the brand drug, and is absorbed at the same rate and to the same extent as the brand drug. This establishes that the generic drug is pharmaceutically equivalent and bioequivalent (together, "therapeutically equivalent") to the brand drug. The FDA assigns generic drugs that are therapeutically equivalent to and are of the same dosage strength and form as their brand counterpart an "AB" rating.

61. Most drug companies that want to introduce a generic drug to the market file an ANDA with the FDA's Center for Drug Evaluation and Research, Office of Generic Drugs. The only exception is for so-called "authorized generics," which are generics launched under the brand company's NDA but typically priced like other generics.

62. Generic drugs that are bioequivalent to a brand drug (sometimes called the "Reference Listed Drug" or "RLD") are assigned a Therapeutic Equivalence Code ("TE Code"). An oral generic drug product will be coded "AB" if bioequivalence is demonstrated. The purpose of this coding is to allow users to determine whether the FDA has evaluated a particular approved product as therapeutically equivalent to other pharmaceutically equivalent products and to provide information on the basis of the FDA's evaluations. Thus, generic drugs that are AB-rated to the brand share the same safety and efficacy characteristics and are the same dosage size

[11] *See* Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

and form.

B. Clobetasol Has Been Sold in the United States for Many Years

63. Defendants are the generic manufacturers of various formulations of Clobetasol in the United States that received FDA approval to market Clobetasol as early as 1996.

64. Taro received FDA approval to market various formulations of Clobetasol in July 1996, November 1998, May 1999, December 2000 and July 2012.

65. Fougera received FDA approval to market various formulations of Clobetasol in February and September 1996, February 1999 and February 2000.

66. Perrigo received FDA approval to market various formulations of Clobetasol in October 1997, March 2008 and August 2012.

67. Morton Grove received FDA approval to market various formulations of Clobetasol in November 1998.

68. Hi-Tech Pharmacal acquired five Abbreviated New Drug Applications for clobetasol propionate .05% (ointment, solution, cream, emulsion cream, and gel) from DFB Pharmaceuticals, Inc. in or around 2009.

C. Clobetasol Prices Increased Dramatically During the Class Period Without Justification

69. Prior to July 2014, the average price in the U.S. paid for Clobetasol was remarkably stable. Between July and October 2014, the prices rose in unison:

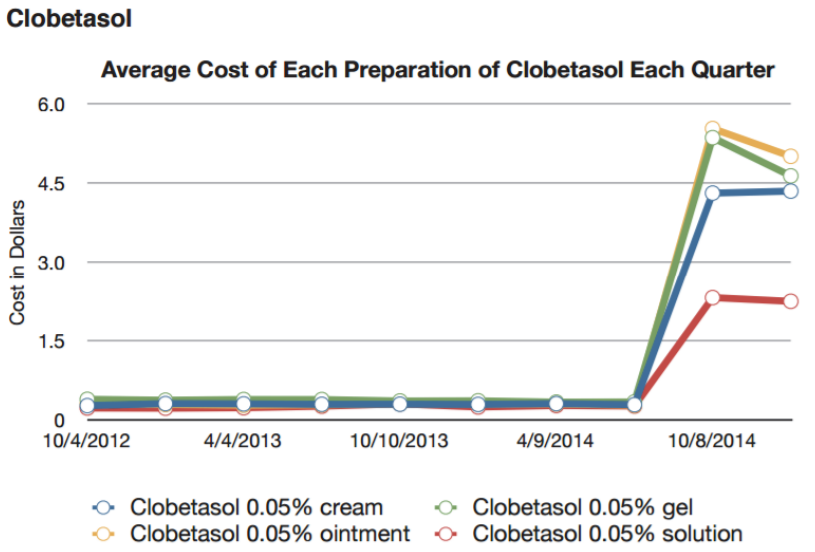


Figure 1: Each preparation of Clobetasol increased dramatically in price between July and October of 2014.

See http://truecostofhealthcare.net/wp-content/uploads/2015/05/Clobetasol.pdf.

70. Beginning in at least July 2014, the price data developed by the National Association of State Medicaid Directors, National Drug Acquisition Cost data ("NADAC")[12] showed that the average price of Clobetasol has increased between 594% and 1967% depending on the formulation:

a. ***Clobetasol 0.05% cream.*** The average price for 15g Clobetasol 0.05% cream increased by 1194%; the average price for 30g Clobetasol 0.05% cream increased by 1154%; the average price for 45g Clobetasol 0.05% cream increased by 1489%; and the average price for 60g Clobetasol 0.05% cream increased by 1492%.

b. ***Clobetasol 0.05% gel.*** The average price for 15g Clobetasol 0.05% gel increased by 979%; the average price for 30g Clobetasol 0.05% gel increased by 1286%; and the average price for 60g Clobetasol 0.05% gel increased by 1967%.

[12] *See* NADAC (National Average Drug Acquisition Cost) weekly reference data from November 2013 to current week available at https://data.medicaid.gov/Drug-Prices/NADAC-National-Average-Drug-Acquisition-Cost-/a4y5-998d.

c. ***Clobetasol 0.05% ointment.*** The average price for 15g Clobetasol 0.05% ointment increased by 1851%; the average price for 30g Clobetasol 0.05% ointment increased by 1838%; the average price for 45g Clobetasol 0.05% ointment increased by 1112%; and the average price for 60g Clobetasol 0.05% ointment increased by 1712%.

d. ***Clobetasol 0.05% solution***. The average price for 25ml Clobetasol 0.05% solution increased by 482%; and the average price for 50ml Clobetasol 0.05% solution increased by 1204%.

e. ***Clobetasol 0.05% emollient.*** The average price for 15g Clobetasol 0.05% emollient increased by 594%; the average price for 30g Clobetasol 0.05% emollient increased by 609%; and the average price for 60g Clobetasol 0.05% emollient increased by 914%.

71. National Average Drug Acquisition Cost ("NADAC") data as of December 21, 2016 demonstrate that Defendants have maintained prices for Clobetasol in all of its relevant forms at supracompetitive prices.[13]

72. The tables below derived from NADAC data on Skin Topicals from the website of The Long Island Dermatological Society[14] show the average "pharmacy cost per package" for the Clobetasol 0.05% Cream National Drug Codes as of September 19, 2013 and March 18, 2015 and illustrate the enormity of the price increases. For example, the average pharmacy cost per package of the first NDC listed rose from $13.80 to $234.83 for the same package.

---

[13] *See* NADAC as of 2016.12.28 based on NADAC (National Average Drug Acquisition Cost) available at https://data.medicaid.gov/Drug-Prices/NADAC-as-of-2016-12-28/bg7x-n8ir at lines 4811 to 4893.

[14] *Available at* http://www.longislanddermatologists.org/default.asp?id=228&c002_ui=sa&c002_id=113#october2014update.

NDC Description	National Drug Code	Brand or Generic	NADAC Per Unit	Units Per Package	Pricing Unit	Average Pharmacy Cost Per Package	Ratio of Recent Cost to Cost 1 Year Prior	Manufacturer or Distributor	Effective (Survey) Date
CLOBETASOL 0.05% CREAM	00168016346	G	0.30668	45.00	GM	$13.80	1.13	E FOUGERA AND CO A DIVISION OF NYCOMED US INC	09/19/2013
CLOBETASOL 0.05% CREAM	50383026745	G	0.30668	45.00	GM	$13.80	1.13	HI-TECH PHARMACAL CO INC	09/19/2013
CLOBETASOL 0.05% CREAM	51672125806	G	0.30668	45.00	GM	$13.80	1.13	TARO PHARMACEUTICALS USA INC	09/19/2013
CLOBETASOL 0.05% CREAM	00168016330	G	0.30304	30.00	GM	$9.09	0.94	E FOUGERA AND CO A DIVISION OF NYCOMED US INC	09/19/2013
CLOBETASOL 0.05% CREAM	50383026730	G	0.30304	30.00	GM	$9.09	0.94	HI-TECH PHARMACAL CO INC	09/19/2013
CLOBETASOL 0.05% CREAM	51672125802	G	0.30304	30.00	GM	$9.09	0.94	TARO PHARMACEUTICALS USA INC	09/19/2013
CLOBETASOL 0.05% CREAM	00168016315	G	0.29679	15.00	GM	$4.45	0.83	E FOUGERA AND CO A DIVISION OF NYCOMED US INC	09/19/2013
CLOBETASOL 0.05% CREAM	50383026715	G	0.29679	15.00	GM	$4.45	0.83	HI-TECH PHARMACAL CO INC	09/19/2013
CLOBETASOL 0.05% CREAM	51672125801	G	0.29679	15.00	GM	$4.45	0.83	TARO PHARMACEUTICALS USA INC	09/19/2013
CLOBETASOL 0.05% CREAM	00168016360	G	0.28562	60.00	GM	$17.14	1.11	E FOUGERA AND CO A DIVISION OF NYCOMED US INC	09/19/2013
CLOBETASOL 0.05% CREAM	50383026760	G	0.28562	60.00	GM	$17.14	1.11	HI-TECH PHARMACAL CO INC	09/19/2013
CLOBETASOL 0.05% CREAM	51672125803	G	0.28562	60.00	GM	$17.14	1.11	TARO PHARMACEUTICALS USA INC	09/19/2013

NDC Description	National Drug Code	NADAC Per Unit	Pricing Unit	Untis Per Package	Brand or Generic	OTC	Ratio of Cost from 10/14 to 4/15	Pharmacy Cost Per Package	Manufacturer or Distributor	Effective (Survey) Date
CLOBETASOL 0.05% CREAM	00168016360	3.91377	GM	60.00	G	N	0.97	$234.83	E FOUGERA AND CO A DIVISION OF NYCOMED US INC	03/18/2015
CLOBETASOL 0.05% CREAM	50383026760	3.91377	GM	60.00	G	N	0.97	$234.83	HI-TECH PHARMACAL CO INC	03/18/2015
CLOBETASOL 0.05% CREAM	51672125803	3.91377	GM	60.00	G	N	0.97	$234.83	TARO PHARMACEUTICALS USA INC	03/18/2015
CLOBETASOL 0.05% CREAM	00168016346	4.31675	GM	45.00	G	N	0.97	$194.25	E FOUGERA AND CO A DIVISION OF NYCOMED US INC	03/18/2015
CLOBETASOL 0.05% CREAM	50383026745	4.31675	GM	45.00	G	N	0.97	$194.25	HI-TECH PHARMACAL CO INC	03/18/2015
CLOBETASOL 0.05% CREAM	51672125806	4.31675	GM	45.00	G	N	0.97	$194.25	TARO PHARMACEUTICALS USA INC	03/18/2015
CLOBETASOL 0.05% CREAM	00168016330	4.35491	GM	30.00	G	N	0.99	$130.65	E FOUGERA AND CO A DIVISION OF NYCOMED US INC	03/18/2015
CLOBETASOL 0.05% CREAM	50383026730	4.35491	GM	30.00	G	N	0.99	$130.65	HI-TECH PHARMACAL CO INC	03/18/2015
CLOBETASOL 0.05% CREAM	51672125802	4.35491	GM	30.00	G	N	0.99	$130.65	TARO PHARMACEUTICALS USA INC	03/18/2015
CLOBETASOL 0.05% CREAM	00168016315	4.43006	GM	15.00	G	N	1.02	$66.45	E FOUGERA AND CO A DIVISION OF NYCOMED US INC	03/18/2015
CLOBETASOL 0.05% CREAM	50383026715	4.43006	GM	15.00	G	N	1.02	$66.45	HI-TECH PHARMACAL CO INC	03/18/2015
CLOBETASOL 0.05% CREAM	51672125801	4.43006	GM	15.00	G	N	1.02	$66.45	TARO PHARMACEUTICALS USA INC	03/18/2015

73. There were no market-based justifications for these abrupt price increases, which were not necessitated by increased manufacturing costs, or research and development costs. There were no known raw material shortages affecting the manufacture of Clobetasol in the United States, nor did demand for Clobetasol suddenly increase.

74. Federal law requires drug manufacturers to report potential drug shortages to the FDA, along with the reasons for those shortages, and their expected duration. Defendants made no such reports with respect to Clobetasol during the Class Period.

75. In a report dated April 21, 2015, Sector & Sovereign Research concluded that: "A plausible explanation is that generic manufacturers . . . are cooperating to raise the prices of

products whose characteristics (low sales due to either very low prices or very low volumes) accommodate price inflation."[15]

76. These price increases had a substantial impact on consumers. Letters from members of Congress to generic drug manufacturers included the following:

> This dramatic increase in generic drug prices results in decreased access for patients. According to the National Community Pharmacists Association (NCPA), a 2013 member survey found that pharmacists across the country "have seen huge upswings in generic drug prices that are hurting patients and pharmacies ability to operate" and "77% of pharmacists reported 26 or more instances over the past six months of a large upswing in a generic drug's acquisition price." These price increases have a direct impact on patients' ability to purchase their needed medications. The NCPA survey found that "pharmacists reported patients declining their medication due to increased co-pays," and "84% of pharmacists said that the acquisition price/lagging reimbursement trend is having a 'very significant' impact on their ability to remain in business to continue serving patients."[16]

77. Defendants' adherence to their price-fixing scheme generated considerable profits. For example, before the price increase in June, Taro's Clobetasol averaged $3 million in weekly gross sales. After the price increase, Taro's weekly gross sales of Clobetasol increased to $20 million, while its market share remained relatively stable during this period.

78. In its annual report for the period ended December 31, 2015, Akorn reported: "Our gross profit increased by $334.7 million, an increase of 128.0% over gross profit of $261.4 million in 2014. Our overall gross profit margin was 60.5% in 2015 compared to 47.1% in 2014." The company attributed the increased profit margin to the effects of "price changes." In its Q2 2016 earnings call with industry analysts on August 4, 2016, Akorn's CFO, Duane

---

[15] *See US Generic Inflation Continues in 1Q15* (Apr. 21, 2015), *available at* http://www.sector-sovereign.com/abccahmck-us-generic-inflation-continues-in-1q15/.

[16] Ltr. from Sen. Sanders and Rep. Cummings to A. Bedrosian (Lannett Pres. and CEO) (Oct. 2, 2014), *available at* http://www.sanders.senate.gov/download/letter-to-mr-bedrosian-president-and-ceo-lannett-company-inc?inline=file.

Portwood, stated: "net revenue for the quarter ended June 30, 2016, was $281 million, an increase of $60 million or 27% over the prior-year quarter. The increase in revenue was driven by organic growth, with approximately two-thirds attributable to price."

79. Similarly, Perrigo reported that gross profit grew by $59 million from 2014 to 2015, primarily due in part to "pricing initiatives" taken in the first quarter of fiscal year 2015 (July-September 2014).

D. Defendants' Opportunities for Collusion

80. The DOJ is reportedly looking closely at trade associations. According to an intelligence report from Policy and Regulatory Report, a source that was given inside information by someone with knowledge of the DOJ's investigation, the DOJ is looking closely "at trade associations as part of their investigation as having been one potential avenue for facilitating the collusion between salespeople at different generic producers."[17]

81. Generic drug manufacturers attend industry trade shows throughout the year, including those hosted by the GPhA, the National Association of Chain Drug Stores, the Healthcare Distribution Management Association (now the Healthcare Distribution Alliance), and Efficient Collaborative Retail Marketing.

82. At these conferences and trade shows, Defendants' representatives have opportunities to interact with each other directly, and discuss their respective businesses and customers. Organized recreational and social events, such as golf outings, lunches, cocktail parties, dinners, and other scheduled activities, are held concurrent with many of these conferences and trade shows, and provide further opportunities for conspirators to meet with

[17] Eric Palmer, *Actavis gets subpoena as DOJ probe of generic pricing moves up food chain*, FIERCEPHARMA (Aug. 7, 2015), *available at* http://www.fiercepharma.com/regulatory/actavis-gets-subpoena-as-doj-probe-of-generic-pricing-moves-up-food-chain.

competitors outside of the usual business setting. Generic drug manufacturer representatives who attend these functions use these opportunities to discuss and share upcoming bids, specific generic drug markets, pricing strategies and pricing terms in their contracts with customers, among other competitively-sensitive information.

83. In addition to these conferences and trade shows, representatives of generic drug manufacturers gather separately, in smaller groups, allowing them to further meet face-to-face with their competitors and discuss their businesses. A large number of generic drug manufacturers, including two of the Defendants, have offices in close proximity to one another in New Jersey, eastern Pennsylvania, or New York, giving them more frequent opportunities to meet and collude. In fact, high-level executives of Defendants gather periodically for what at least some of them refer to as "industry dinners."

84. As a result of these various interactions, Defendants' sales and marketing executives are well aware of their competition and, more importantly, each other's current and future business plans. This familiarity and these opportunities often lead to agreements among competitors to fix prices or to allocate given markets, so as to avoid price competition.

85. Defendants routinely communicate and share information with each other about their bids and pricing strategies. This can include forwarding bid packages received from their customers (*e.g.*, Requests for Proposal) to competitors, either on their own initiative, or at the competitor's request.

86. Defendants also share information regarding the terms of their contracts with customers, including terms relating to pricing, price protection and rebates. Generic drug manufacturers use this information from their competitors to impose higher prices or more onerous terms on their customers, to the ultimate detriment of consumers.

87. Before July 2014, the price of Clobetasol was stable. Following their June 2014 GPhA meeting, which was attended by executives from all of the Defendants, Defendants caused the price of Clobetasol to dramatically increase in unison beginning in at least July 2014. The increases were the result of a horizontal agreement among Defendants to increase pricing and restrain competition for Clobetasol. Defendants met at least twice in 2014 before implementing their price increases. Both meetings occurred at GPhA events.

88. The GPhA describes itself as "the nation's leading trade association for manufacturers and distributors of generic prescription drugs, manufacturers of bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic industry." *See* http://www.gphaonline.org/about/the-gpha-association/. GPhA was formed in 2000 from the merger of three industry trade associations: GPhA, the National Association of Pharmaceutical Manufacturers, and the National Pharmaceutical Alliance.

89. According to GPhA's website, "GPhA member companies supply approximately 90 percent of the generic prescription drugs dispensed in the U.S. each year." *See* http://www.gphaonline.org/about/membership. GPhA further claims that, "[b]y becoming part of GPhA, you can participate in shaping the policies that govern the generic industry and help secure the future of this vital pharmaceutical market segment. In addition, GPhA provides valuable membership services, such as business networking opportunities, educational forums, access to lawmakers and regulators, and peer-to-peer connections." *Id*.

90. All Defendants are members of the GPhA.

91. Defendants Hi-Tech, Perrigo, Fougera, Taro and Morton Grove each attended the GPhA annual meeting in Orlando, Florida on February 19, 20 and 21, 2014.

92. Defendants Hi-Tech, Perrigo, Fougera, Taro, and Morton Grove then attended the GPhA's CMC Workshop in North Bethesda, Maryland on June 3 and June 4, 2014 ("GPhA CMC Meeting").

93. The meetings, among other contacts among Defendants, provided Defendants with opportunities to collude, and on information and belief, at these meetings Defendants agreed to increase pricing for Clobetasol. Soon after the GPhA CMC Meeting, Defendants caused the prices for Clobetasol to increase by extraordinary amounts.

D. Government Responses to Rising Generic Drug Prices

94. As noted above, generic manufacturers' conduct in regards to generic drug price increases is under investigation by Congress, the DOJ, state attorneys general and others.

95. On October 2, 2014, U.S. Senator Bernie Sanders and U.S. Congressman Elijah Cummings sent letters to several generic drug manufacturers requesting detailed sales, marketing and cost information for numerous generic products. Each letter raised significant concerns about the extraordinary price increases that many generic products had experienced since 2013.[18]

96. On November 20, 2014, United States Senator Bernie Sanders' Senate Subcommittee on Primary Health and Aging held a hearing entitled "Why Are Some Generic Drugs Skyrocketing In Price?"[19]

---

[18] *Available at* http://www.sanders.senate.gov/newsroom/press-releases/congress-investigating-why-generic-drug-prices-are-skyrocketing.

[19] *See*, *e.g.*, U.S. Congress Press Release, *Congressional Panel to Probe Generic Drug Price Hikes* (Nov. 11, 2014), *available at* https://democrats-oversight.house.gov/news/press-releases/congressional-panel-to-probe-generic-drug-price-hikes.

97. Most recently, in December 2016, the United States Senate Special Committee on Aging issued a lengthy report on drug pricing noting that its investigation "uncovered disturbing practices in pharmaceutical drug pricing."[20]

98. No later than November 3, 2014, as noted above, the DOJ opened a wide-ranging grand jury investigation into the marketing and pricing practices of generic drugs, which has resulted in the issuance of grand jury subpoenas several generic drug manufacturers, including all Defendants and/or their affiliates. The DOJ is now conducting a wide-ranging criminal investigation into collusion among generic drug companies. According to BLOOMBERG NEWS, the investigation encompasses more than 12 companies and at least 24 generic drugs. *See*, https://www.bloomberg.com/news/articles/2016-12-22/widespread-drug-price-increases-point-to-collusion-study-finds.

99. A source at the Policy and Regulatory Report says "prosecutors see the case much like its antitrust probe of the auto parts industry, which has gone on for years and morphed into the department's largest criminal antitrust probe ever. Like in that case, prosecutors expect 'to move from one drug to another in a similar cascading fashion.'"[21]

100. Some Defendants have confirmed that they have been served with federal grand jury subpoenas and subpoenas issued by the Connecticut Office of the Attorney General.

---

[20] United States Senate Special Committee on Aging, Sudden Price Spikes in Off-Patent Prescription Drugs: The Monopoly Business Model that Harms Patients, Taxpayers, and the U.S. Health Care System (Dec. 2016), *available at* https://www.collins.senate.gov/sites/default/files/DP%20Report.pdf.

[21] Eric Palmer, *DOJ criminal probe takes a look at trade associations*, FIERCEPHARMA (Jul. 10, 2015), *available at* http://www.fiercepharma.com/regulatory/doj-criminal-probe-takes-a-look-at-trade-associations.

101. On September 9, 2016, Taro disclosed in an SEC filing that "Taro Pharmaceuticals, U.S.A., Inc. . . . as well as two senior officers in its commercial team, received grand jury subpoenas from the United States Department of Justice, Antitrust Division, seeking documents relating to corporate and employee records, generic pharmaceutical products and pricing, communications with competitors and others regarding the sale of generic pharmaceutical products and certain other related matters.

102. According to a BLOOMBERG NEWS article, Sandoz has confirmed that, it received a subpoena from the DOJ in March 2016, and stated that it believed the subpoena was related to "the industry-wide investigation into generic drug pricing in the U.S."[22]

103. The fact that these companies and/or their employees received subpoenas from a federal grand jury is significant, as is reflected in Chapter 3 of the 2014 edition of the DOJ's Antitrust Division Manual.[23] Section F.1 of that chapter notes that "staff should consider carefully the likelihood that, if a grand jury investigation developed evidence confirming the alleged anticompetitive conduct, the Division would proceed with a criminal prosecution." *Id.* at III-82. The staff request needs to be approved by the relevant field chief and is then sent to the Antitrust Criminal Enforcement Division. *Id.* "The DAAG [Deputy Assistant Attorney General] for Operations, the Criminal DAAG, and the Director of Criminal Enforcement will make a recommendation to the Assistant Attorney General. If approved by the Assistant Attorney General, letters of authority are issued for all attorneys who will participate in the grand jury investigation." *Id.* at III-83. "The investigation should be conducted by a grand jury in a judicial

[22] *Available at* https://www.bloomberg.com/news/articles/2016-11-17/nypd-union-goes-after-drug-prices-amid-doj-pharma-investigation.

[23] DOJ Antitrust Division Manual, *available at* http://www.justice.gov/atr/public/divisionmanual/chapter3.pdf.

district where venue lies for the offense, such as a district from or to which price-fixed sales were made or where conspiratorial communications occurred." *Id.* Thus, Defendants' and their representatives' receipt of federal grand jury subpoenas is an indication that antitrust offenses have occurred.

104. If there is a leniency applicant involved in the DOJ generic drug investigation, there is still greater indication that antitrust offenses have occurred. The DOJ notes on its website that the leniency applicant must admit to a criminal violation of the antitrust laws before receiving a conditional leniency letter.

> The Division's leniency policies were established for corporations and individuals "reporting their illegal antitrust activity," and the policies protect leniency recipients from criminal conviction. Thus, the applicant must admit its participation in a criminal antitrust violation involving price fixing, bid rigging, capacity restriction, or allocation of markets, customers, or sales or production volumes before it will receive a conditional leniency letter. Applicants that have not engaged in criminal violations of the antitrust laws have no need to receive leniency protection from a criminal violation and will receive no benefit from the leniency program.[24]

105. The DOJ further provides that the leniency applicant must also satisfy the following condition, among others, to avail itself of the government's leniency: "[t]he confession of wrongdoing is truly a corporate act, as opposed to isolated confessions of individual executives or officials." *Id*.

106. The DOJ is poised to issue criminal indictments against various companies and individuals growing out this investigation and, as indicated above, issued its first two indictments on December 12, 2016. On December 14, 2016, BLOOMBERG reported that "[t]he Justice

[24] Frequently Asked Questions Regarding The Antitrust Division's Leniency Program, *available at* http://www.justice.gov/atr/frequently-asked-questions-regarding-antitrust-divisions-leniency-program.

Department accused two executives of colluding with other generic pharmaceutical companies to fix prices, the first criminal charges stemming from a sweeping two-year investigation. Jeffrey Glazer, a former chief executive officer of Heritage Pharmaceuticals Inc., and Jason Malek, an ex-president, were charged in Philadelphia on Wednesday, according to court filings."[25]

107. Twenty states attorneys general also filed their first action (relating to the generic drugs Glyburide and Doxycycline) based on their investigation into generic drug pricing on December 15, 2016.[26] They have indicated that more actions are likely to follow, specifically alleging that they "have uncovered a wide-ranging series of conspiracies implicating numerous different drugs and competitors, which will be acted upon at the appropriate time..." The states attorneys general describe these conspiracies as "schemes to fix and maintain prices, allocate markets and otherwise thwart competition" and explain that they are carried out by generic companies through their senior executives who "exploit their interactions at various and frequent industry trade shows, customer conferences and other similar events, to develop relationships and sow the seeds for their illegal agreements. The anticompetitive agreements are further refined and coordinated at regular 'industry dinners', 'girls nights out', lunches, parties, and numerous and frequent telephone calls, emails and text messages."[27]

108. Connecticut's attorney general George C. Jepsen commented on the suit that it was "just the tip of the iceberg" and stressed that "our investigation is continuing, and it goes

---

[25] Tom Schoenberg, *U.S. Generic Drug Probe Seen Expanding After Guilty Pleas*, BLOOMBERG (Dec. 14, 2016), *available at* https://www.bloomberg.com/news/articles/2016-12-14/u-s-files-first-charges-in-generic-drug-price-fixing-probe.

[26] Complaint, *State of Connecticut v. Aurobindo Pharma USA*, 16-cv-2056-VLB (D. Conn. Dec. 15, 2016), ECF No. 1.

[27] *Id.* at paragraphs 7-8.

way beyond the two drugs in this lawsuit" and "involves many more companies" than were named in the first complaint.[28]

E. The Clobetasol Market is Conducive to an Effective Conspiracy.

109. Characteristics specific to the market for Clobetasol in the United States make it conducive to a price-fixing agreement. As the dominant players in the Clobetasol market, Defendants were able to fix, raise, and maintain their prices for Clobetasol without competitive threats from rival generic manufacturers.

110. **The Market is Highly Concentrated:** A concentrated market is more susceptible to collusion and other anticompetitive practices. The Clobetasol market is highly concentrated and is dominated by a handful of companies: Hi-Tech, Perrigo, Fougera, Taro and Morton Grove. Therefore, elaborate communications, quick to be detected, would not have been necessary to enable pricing to be coordinated.

111. **The Market has High Barriers to Entry:** Conspiracies that raise product prices above competitive levels will, all things being equal, attract to the relevant market new firms seeking to benefit from supracompetitive prices. But when barriers to entering the market are significant, new firms are less likely to do so. Barriers to entry thereby facilitate the maintenance of a price-fixing conspiracy. Costs of manufacture, intellectual property, and expenses related to regulatory oversight are barriers to entry.

112. **Demand for Clobetasol is Inelastic:** "Elasticity" is a term that describes the sensitivity of demand for a product to changes in its price. Demand is "inelastic" if an increase in its price results in a relativity small decline in demand for the product. Demand is inelastic in

[28] Katie Thomas, *20 States Accuse Generic Drug Companies of Price Fixing*, THE NEW YORK TIMES (Dec. 15, 2016), *available at* http://www.nytimes.com/2016/12/15/business/generic-drug-price-lawsuit-teva-mylan.html.

markets—such as the Clobetasol market—in which customers cannot readily substitute alternative products, or do without a product altogether.

113. For competitors to profit from colluding to raise prices above competitive levels, demand for their product must be relatively inelastic at competitive prices. Otherwise, increased prices would reduce their sales as customers abandoned their products. Inelastic demand thus facilitates collusion.

114. Demand for Clobetasol is highly inelastic. A meaningful increase in the price for Clobetasol would not induce purchasers to switch to another product in significant numbers, as the there is no reasonable substitute for Clobetasol available at a lower price.

115. **Clobetasol is a Fungible Product:** Because all Clobetasol is the same, price is the predominant factor driving customers' purchasing decisions. The interchangeability of Clobetasol products facilitated Defendants' conspiracy by enabling coordination on price that would be more difficult if Defendants sold products that varied in composition and/or performance.

116. **Defendants Had Ample Opportunities To Meet and Conspire:** Defendants had numerous opportunities to conspire in person under the guise of legitimate business meetings. In particular, Defendants are members of the GPhA, and attend other industry events and meetings, which provide opportunities to communicate. Defendants' representatives regularly attended meetings of GphA and meetings of other trade associations during the Class Period. The DOJ is reportedly investigating trade associations like GPhA as a potential avenue for facilitating collusion among generic drug manufacturers as part of its ongoing investigation into anticompetitive pricing activities in generic drug markets.

ANTITRUST INJURY

117. During the Class Period, Plaintiff and Class Members purchased Clobetasol directly from Defendants. As a result of the Defendants' anticompetitive conduct, Plaintiff and Class Members paid more for Clobetasol than they would have and thus suffered substantial damages. This is a cognizable antitrust injury and constitutes harm to competition under the federal antitrust laws.

118. Because Defendants' unlawful conduct has successfully restrained competition in the market, Plaintiff and Class Members have sustained, and continue to sustain, significant losses in the form of artificially inflated prices paid to Defendants. The full amount of such damages will be calculated after discovery and upon proof at trial.

119. Defendants' anticompetitive conduct is ongoing, and as a result Plaintiff and the Class continue to pay supracompetitive prices for Clobetasol.

CLAIM FOR RELIEF

VIOLATION OF SECTION 1 OF THE SHERMAN ACT, 15 U.S.C. § 1

120. Plaintiff incorporates and re-alleges, as though fully set forth herein, each of the paragraphs set forth above.

121. Defendants are *per se* liable under Section 1 of the Sherman Act, 15 U.S.C. § 1, for the injuries and damages caused by their contract, combination, and conspiracy in restraint of trade as alleged herein.

122. There is no legitimate, non-pretextual, procompetitive business justification for Defendants' conspiracy that outweighs its harmful effect. Even if there were some conceivable justification, the conspiracy is broader than necessary to achieve such a purpose.

123. As set forth above, in violation of Section 1 of the Sherman Antitrust Act, Defendants entered into agreements with one another as to the output and pricing of Clobetasol in the United States. This conspiracy was *per se* unlawful price-fixing, or alternatively, was an unlawful restraint of trade under the rule of reason.

124. Each Defendant has committed at least one overt act to further the conspiracy alleged in this Complaint.

125. The conspiracy had its intended effect, as Defendants benefited from their collusion and the restraint of competition, both of which artificially inf1ated the prices of Clobetasol, as described herein.

126. As a result of Defendants' unlawful conduct, Plaintiff and Class Members have been injured in their business and property in that they have paid more for Clobetasol than they otherwise would have paid in the absence of Defendants' unlawful conduct. The full amount of such damages is presently unknown but will be determined after discovery and upon proof at trial.

127. Defendants' unlawful conduct as alleged herein poses a significant, continuing threat of antitrust injury for which injunctive relief is appropriate under Section 16 of the Clayton Act.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff and Class Members pray for relief as set forth below:

A. Certification of the action as a Class Action pursuant to Federal Rule of Civil Procedure 23, and appointment of Plaintiff as Class Representative and its counsel of record as Class Counsel;

B. Permanent injunctive relief that enjoins Defendants from violating the antitrust

laws and requires them to take affirmative steps to dissipate the effects of their violations;

C. That acts alleged herein be adjudged and decreed to be unlawful restraints of trade in violation of the Sherman Act, 15 U.S.C. § 1;

D. A judgment against Defendants, jointly and severally, for the damages sustained by Plaintiff and the Class defined herein, and for any additional damages, penalties, and other monetary relief provided by applicable law, including treble damages;

E. By awarding Plaintiff and Class Members pre-judgment and post-judgment interest as provided by law, and that such interest be awarded at the highest legal rate from and after the date of service of the Complaint in this action;

F. The costs of this suit, including reasonable attorney fees; and

G. Such other and further relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff, on behalf of itself and others similarly situated, hereby requests a jury trial, pursuant to Federal Rule of Civil Procedure 38, on any and all claims so triable.

Dated: December 31, 2016

Respectfully submitted,

/s/ Linda P. Nussbaum

Linda P. Nussbaum
Bart D. Cohen
Bradley J. Demuth
Peter E. Moran
NUSSBAUM LAW GROUP, P.C.
1211 Avenue of the Americas
40th Floor
New York, NY 10036-8718
(917) 438-9189
lnussbaum@nussbaumpc.com
(917) 438-9198
bcohen@nussbaumpc.com

Juan R. Rivera Font
JUAN R. RIVERA FONT LLC
Ave. González Giusti #27, Suite 602
Guaynabo, PR 00968
(787) 751-5290
juan@riverafont.com

Counsel for Plaintiff César Castillo, Inc. and the Proposed Direct Purchaser Class